STERIS®

K111810

SEP - 2 2011

510(k) Summary
For
Amsco® V-PRO™ 1 and V-PRO™ 1 Plus Low Temperature Sterilization Systems

STERIS Corporation
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Senior Director, FDA Regulatory Affairs
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Submission Date: June 24, 2011

K111810

SEP - 2 2011

1. Device Name

Trade Name:	Amsco V-PRO 1 Low Temperature Sterilization System and Amsco V-PRO 1 Plus Low Temperature Sterilization System
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas
Classification Number:	21 CFR 880.6860
Product Code:	MLR

2. Predicate Device

Amsco® V-PRO™ 1 Low Temperature Sterilization System (K062297)

Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System (K083097)

3. Description of Device

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilizers are self-contained stand-alone devices using vaporized hydrogen peroxide. These devices are intended for use in terminal sterilization of cleaned, rinsed and dried, reusable medical devices used in healthcare facilities. The sterilizers operate at low pressure and low temperature and are therefore suitable for processing medical devices sensitive to heat and moisture.

4. Intended Use

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems, with VAPROX HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 1 Cycle, which is identical to the V-PRO 1 Plus Lumen Cycle, was cleared under K062297 and can sterilize:*

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors

- Medical devices with a single stainless steel lumen with:
  - an inside diameter of 1 mm or larger and a length of a 125 mm or shorter
  - an insider diameter of 2 mm or larger and a length of 250 mm or shorter
  - an inside diameter of 3 mm or larger and a length of 400 mm or shorter

* The validation testing for all lumen sizes was conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO 1 Plus Low Temperature Sterilization System's Non Lumen Cycle was cleared under K083097 and can sterilize:**

Non-lumened instruments including non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

** The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

5. Description of Safety and Substantial Equivalence

The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems are the same as the predicate devices (K062297 and K083097). Minor modifications are proposed to the device software and hardware that collectively address customer requests and enhance device usability. The following performance testing has been completed to ensure substantial equivalence.

Device Modification	Testing	Acceptance Criteria	Results
Odor Filter	Filters were tested running continuous Non-Lumen cycles.	Oil smell shall not be present in devices using the proposed filter before that observed for devices using the current filter.	**PASS**
Vacuum pump oil	Testing was performed concurrently with the ARS Filter testing.	For devices using the proposed oil, oil smell shall not be detected before or at higher levels that that observed for devices using the current oil. No alarms or failures shall be observed during testing.	**PASS**
ARS Filter	Nine filters of each variety of were run either until an oil smell was detected or 750 cycles were reached.	The proposed ARS filters perform equally to or better than the current ARS filters.	**PASS**
Gas Ballast Filter	The proposed filters (a total of 5) was tested by running until a failure was detected.	The proposed filters perform equally to or better than the current filters.	**PASS**
Software Modifications	Software Validation	Software shall be appropriately verified and validated.	**PASS**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Robert Sullivan
Senior Director, FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060

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Re: K111810
Trade/Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: August 5, 2011
Received: August 8, 2011

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

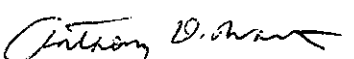
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Amsco® V-PRO™ 1 Low Temperature Sterilization System
Amsco® V-PRO™ 1 Plus Low Temperature Sterilization System

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The Amsco V-PRO 1 and V-PRO 1 Plus Low Temperature Sterilization Systems, with VAPROX HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO 1 Cycle, which is identical to the V-PRO 1 Plus Lumen Cycle, was cleared under K062297 and can sterilize:*

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** The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Wilk

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111810